EXHIBIT V

FDA LETTER LIFING CLINICAL HOLD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

IND 52,791

MAY 23 1997

Schering Corporation
Attention: Joseph Lamendola, Ph.D.
Galloping Hill Road
Kenilworth, NJ 07033

2436 0050

Dear Dr. Lamendola:

Please refer to your Investigational New Drug Application (IND) submitted February 28, 1997, pursuant to section of 505(I) of the Federal Food, Drug, and Cosmetic Act for the preparation SCH 58235 Capsules, IND 52,791.

We also refer to your amendment dated April 22, 1997, which provided a full response to our April 4, 1997, letter which cited the reasons for placing this IND on clinical hold and the information needed to resolve the clinical hold issues.

We have completed the review of your submission, and have concluded that it is reasonably safe to initiate clinical trials as we told you in our May 16, 1997, telephone conversation.

We have the following comments and recommendations, however, regarding your study protocol:

As explained to you, the clinical hold may be lifted provided you are willing to make the following safety changes to protocol C96-345 and its screening study, C96-411.

1. To help clarify the hepatotoxicity issue, and for safety purposes, only patients with normal hepatobiliary function should be randomized into the trial.

2. GGT should be added to the extended safety profile.

3. In patients who prematurely discontinue the study for any reason, a liver function profile (AST, ALT, total bilirubin, alkaline phosphatase and GGT) should be obtained on the last day of study participation. If values are elevated, they should be followed at a minimum of weekly intervals until they return to normal.

4. In addition, please submit final safety data from the already completed clinical trials as soon as possible.

We should also clarify a point in our April 4, 1997, clinical hold letter that the request to submit results of the sponsor's interim analysis and submission of CV's for all investigators refers to protocols C96-411 and C96-345, and are not, therefore, issues that need to be resolved to lift the clinical hold.

As sponsor of this IND, you are responsible for compliance with the Federal Food, Drug, and Cosmetic Act and regulations promulgated thereunder (Title 21 of the Code of Federal Regulations). Those responsibilities include reporting any unexpected fatal or life-threatening experiences by telephone to this Agency no later than 3 working days after receipt of the information (21 CFR 312.32).

If you have any questions, please contact Ms. Margaret Simoneau, R.Ph., Consumer Safety Officer, at 301-443-3510.

Sincerely yours,

Solomon Sobel, M.D.
Director
Division of Metabolism and
Endocrine Drug Products (HFD-510)
Office of Drug Evaluation II
Center for Drug Evaluation and Research